

DETAILED ACTION

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-34, drawn to a composition comprising a polyglucose and optionally, salts thereof and sorbic acid, or a salt thereof.

Group II, claim(s) 35 and 37-44, drawn to a method of treating, alleviating, or preventing HIV-1 or a related virus or other sexually transmitted diseases comprising administering a polyglucose and optionally, salts thereof and sorbic acid.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature of the inventions of Groups I and II is the composition comprising a polyglucose and optionally, salts thereof and sorbic acid or a salt thereof. Said composition comprising the polyglucose hyaluronic acid, the polyglucose dextrin, and optionally potassium sorbate is a known product. See Mastradonato et al. (US Patent Application Publication US 2002/0173485, provided by Applicant in IDS filed 06 Apr 2006), page 2, paragraph 20, lines 2 and 13. Therefore said composition is not the special technical feature of a single general inventive concept. The special technical feature of the invention of Group I is the specific chemical structure of the polyglucose. The special technical feature of the invention of Group II is the specific method of treating a specific disease using a composition comprising a specific polyglucose.

Species Election Requirement

The invention of Group II in this application contains claims directed to more than one species of diseases the generic invention. These species of diseases are deemed to lack unity of invention because they are not so linked as to form a single general

inventive concept under PCT Rule 13.1. If Applicant restricts to the invention of Group II, Applicant is further required to elect from the following species election.

The species of diseases are as follows, disclosed in claims 35 and 41:

HIV-1 or a related virus,

bacterial vaginosis,

Chlamydia,

genital herpes,

genital warts,

gonorrhea,

syphilis,

trichomoniasis, or

Candida.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The claims are deemed to correspond to the species listed above in the following manner:

Claims 35 and 37-44 are generic to the species of disease.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The common feature of the inventions of Group II is the composition comprising a polyglucose and optionally, salts thereof and sorbic acid or a salt thereof. Said composition comprising the polyglucose hyaluronic acid, the polyglucose dextrin, and optionally potassium sorbate is a known product. See Mastradonato et al. (US Patent Application Publication US 2002/0173485, provided by Applicant in IDS filed 06 Apr 2006), page 2, paragraph 20, lines 2 and 13. Therefore said composition is not a single general inventive concept. The special technical feature of the invention of Group II is the specific method of treating a specific disease using a composition comprising a specific polyglucose.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JSL

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614